

REMARKS

Claims 1-41 are pending. Claims 1, 17 and 31 have been revised as presented above. The claim revisions better tailor the claims to currently contemplated commercial embodiments of the claimed subject matter. Thus the revisions are made to expedite prosecution for business reasons rather than in acquiescence to any alleged rejection of record. Support for the revisions is found throughout the application and claims as filed.

Applicants expressly reserve the right to re-present the subject matter no longer within the scope of the revised claims in a continuing application without prejudice.

No new matter has been added, and entry of the revised claims is respectfully requested.

Alleged Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-41 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking reasonable enablement for preventing inflammation. The Examiner acknowledges, however, that the specification is enabling for reducing or treating inflammation. Applicants respectfully traverse this rejection.

Without acquiescence to the instant rejection, the claims have been revised as presented above for business purposes. The amendments render this rejection moot.

In view of the above, Applicants respectfully submit that this rejection can be withdrawn.

Alleged Rejection Under 35 U.S.C. § 103 (a)

Claims 1-26 and 29-41 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over WO 98/34644 (the '644 application) for reasons already of record. Briefly, the Examiner alleges that the cited art teaches the concept of exposing a damaged tissue to a low dose photosensitizing agent or low dose light in order to reduce inflammation associated with photodynamic therapy. According to the Examiner, the concept of treating or reducing inflammation caused by photodynamic therapy by modifying the light or concentration is therefore taught by the cited art. Applicants traverse this rejection for the reasons already of record as well as those discussed below.

Applicants respectfully submit that the '644 application fails to render the claimed methods *prima facie* obvious because this reference simply fails to teach or suggest the claimed methods. The instant claims are directed to a *two-step* dose of light treatments to treat inflammation. In the first step, a normal dose of light treatment is administered to tissue sensitized with a photosensitizing agent, *i.e.*, photodynamic therapy (PDT) is administered. In the second step, a *reduced dose* of light is administered to the same tissue. The second, reduced dose of light is administered without any additional photosensitizing agent and results in reduced inflammation in the treated tissue. In contrast, the '644 application reports that low-dose photodynamic therapy is used to reduce or prevent inflammation in a tissue in the absence of any other photodynamic therapy. *See, e.g.*, the '644 application at page 17, lines 3-19.

In other words, the '644 application reports use of a *single, low-dose* treatment of tissue contacted with a photosensitizing agent with light that activates that agent. The '644 application reports that this method of single, low-dose light treatment is useful in treating or preventing inflammation caused by physical agents or biological agents. *See, e.g., id.* at page 19, lines 5-9. But the '644 application fails to teach, suggest, or otherwise indicate that a second, low-dose PDT can reduce or treat inflammation caused by an earlier, normal dose PDT. In fact, and contrary to the instant rejection's assertions, there is no teaching or suggestion in the '644 application that normal dose PDT results in inflammation (see Applicants' response filed August 21, 2006, paragraph bridging pages 8 and 9). The instant rejection, including the Action mailed October 30, 2006, fails to address this critical deficiency.

Nowhere in the '644 application is there recognition that a *second* administration of low-dose light in the absence of any additional photosensitizing agent can reduce or treat inflammation resulting from normal dose photodynamic therapy. The mere disclosure that low-dose photodynamic therapy can reduce inflammation generally fails to provide a rationale, scientific basis to assert that a low-dose light treatment will reduce inflammation resulting from a normal dose of photodynamic therapy. Indeed, there is no disclosure or suggestion that inflammation due to normal dose PDT is equivalent to inflammation due to a physical or biological agent as reported in the '644 application. Therefore, the instant rejection's general assertion of obvious to treat

inflammation with low dose PDT is based upon improper *speculation* of equivalency between all forms of inflammation.

But this speculation is not supported by any evidence of record. Indeed, and as noted above, the '644 application is silent on whether normal dose PDT even causes inflammation.

In the absence of evidence supporting equivalency, the skilled person in the relevant field would have no expectation of success in using a second dose of PDT to reduce inflammation due to a first dose of PDT. The lack of a reasonable expectation of success also results in the instant rejection being based upon an impermissible "obvious to try" standard. Each of the lack of a reasonable expectation of success, and the application of an impermissible "obvious to try" standard, is sufficient to prevent establishment of a *prima facie* case of obviousness. The presence of both factors strongly indicates that no issue of obviousness is present.

Moreover, and given the inflammatory response to normal dose photodynamic therapy, a person of ordinary skill in the art is likely to surmise that the use of more PDT following normal dose PDT would result in more inflammation. The instant rejection provides no reason for the skilled artisan to expect that more PDT would reduce inflammation rather than increase inflammation. With this in mind, Applicants point out that the claimed subject matter is based upon an unexpected discovery relating to PDT induced inflammation. This unexpected result is sufficient to defeat any allegation of obviousness.

In view of the above, Applicants respectfully submit that no *prima facie* case of obviousness is present, and the instant rejection should be removed.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **273012011800**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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